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(54) Abstract Title
Dressings for the treatment of exuding wounds

(57) The invention provides a layered wound dressing material comprising: a wound facing hydrogel layer (9) and a barrier layer, wherein the barrier layer comprises a pH-sensitive material that is substantially insoluble in water at 25°C under acidic conditions, but substantially soluble in water at 25°C under neutral or alkaline conditions. In use, the hydrogel layer (9) absorbs and is gradually neutralized by wound exudate until its pH rises to a level that causes dissolution of the barrier layer, thereby allowing excess exudate to flow out from the hydrogel layer. The invention further provides wound dressings comprising such barrier layers and methods of use of such dressings.

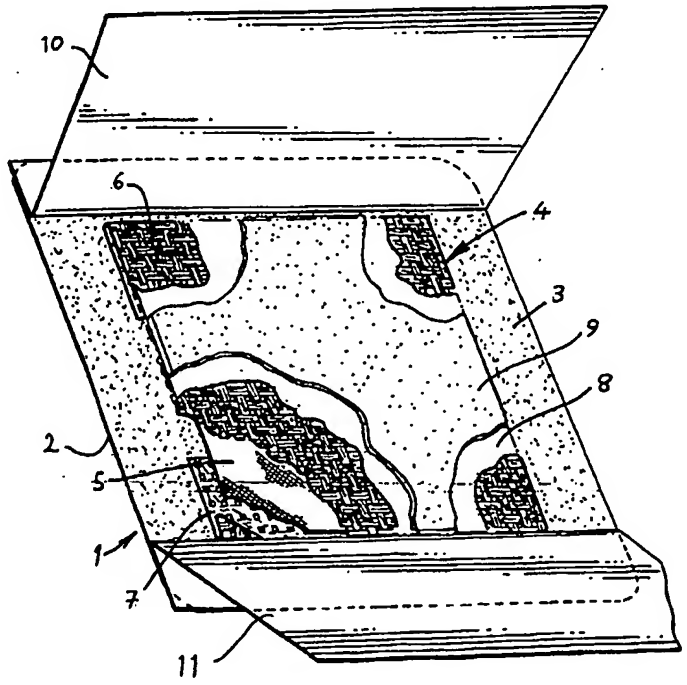

Fig. 1

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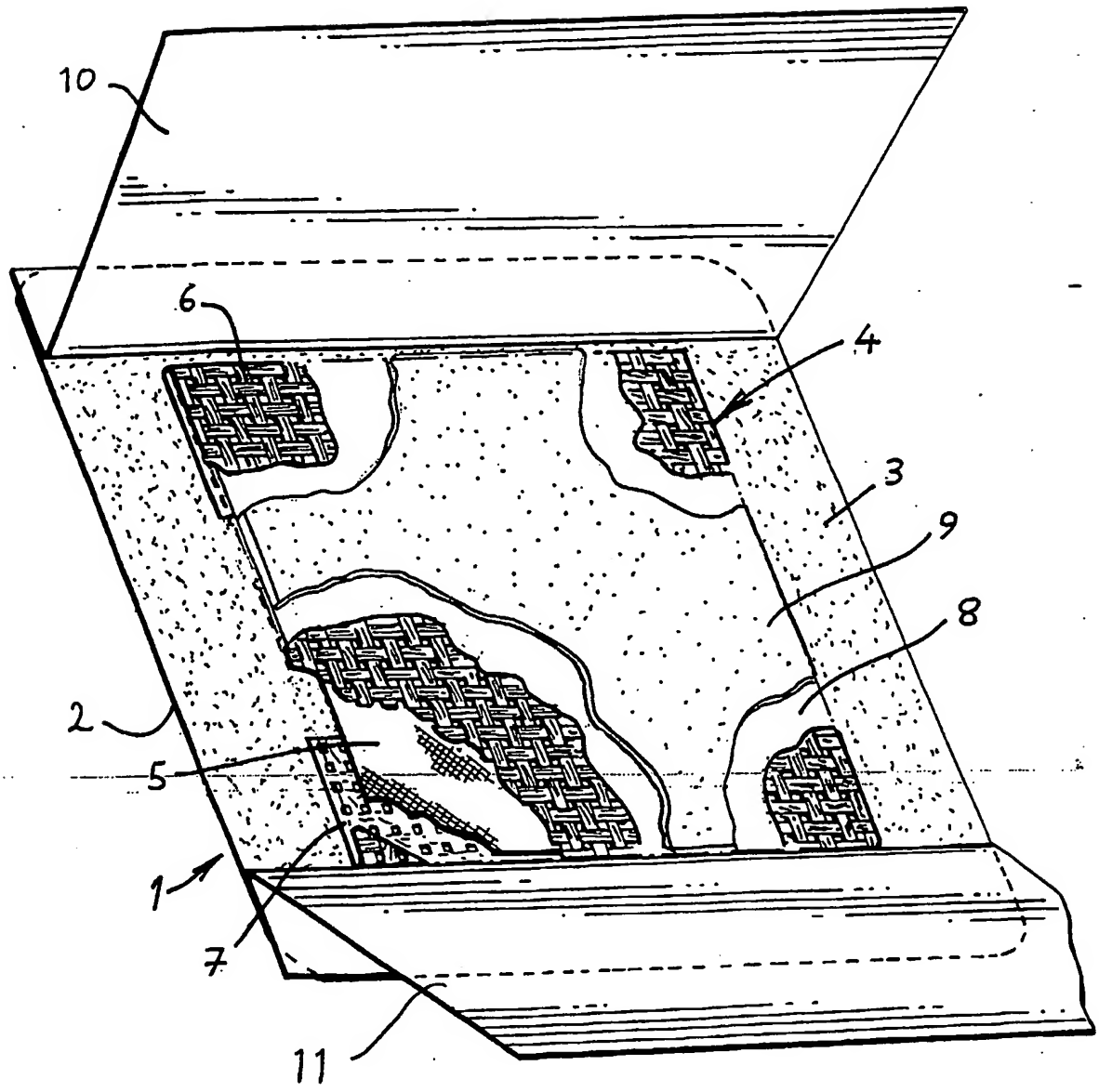

Fig. 1

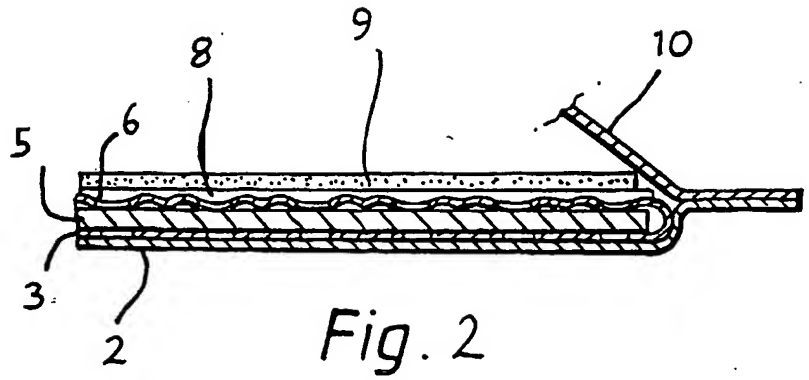

Fig. 2

DRESSINGS FOR THE TREATMENT OF EXUDING WOUNDS

The present invention relates to wound dressings, and in particular to a new layered wound dressing structure.

It is known that the maintenance of a moist wound environment promotes the healing of wounds, especially burns and chronic wounds such as ulcers. However, it is also desirable to avoid excessive moisture or pooling of wound exudate on the wound, since liquid exudate causes maceration of skin adjacent to the wound and other difficulties. Furthermore, liquid exudate can leak from the wound site and contaminate clothes or bedding.

In practice, it is difficult to maintain the desired moisture level at the wound site because the rate of wound fluid production varies from wound to wound, and over time for any single wound. This can necessitate frequent dressing changes and a range of dressing types to treat different wounds. For example, infected wounds generally produce substantially more exudate than non-infected wounds. Surgical wounds have an acute inflammatory phase of a few days during which discharge is significant, after which the rate of exudate production can be expected to fall sharply.

Studies have been carried out on the pH of the wound environment during wound healing. Whilst it is no simple matter to determine the actual pH at a wound site, it appears that the pH of chronic wounds is neutral or slightly alkaline, whereas the pH of intact skin is slightly acidic (pH 4 or 5). It also appears that prolonged acidification of chronic wound surfaces using acid buffered solutions increases the healing rate. However, it is not practical or desirable to irrigate chronic wounds with acid-buffered solutions in normal medical practice.

US-A-4813942 describes a debridement wound dressing comprising a hydrocolloid wound contacting layer containing 35% to 50% w/w of pectin or other hydrocolloids capable of reducing the pH of the wound/dressing interface to 4.8-

6.5. The debridement dressing is left in place for 24-48 hours, and is then replaced by a regeneration wound dressing that provides near-neutral pH at the wound surface.

Antimicrobial wound dressings containing antibiotics or other antimicrobial therapeutic agents for the treatment of infected wounds are known. However, such dressings are not indicated for prophylactic use on wounds that are not obviously infected, because of concerns about microbial resistance and risks of unnecessary medication. A need exists for new wound dressings that address these concerns.

It is an object of the present invention to provide structures for use as or in improved multilayer dressings for the treatment of a wide range of wounds.

It is a further object of the present invention to provide layered wound dressing structures that can maintain a lowered pH at the surface of a wound to assist wound healing.

It is a further object of the present invention to provide layered wound dressing structures that can release active therapeutic agents selectively into exuding wounds.

The present invention provides a layered wound dressing material comprising a wound facing hydrogel layer and a barrier layer, wherein the barrier layer comprises a pH-sensitive material that is more soluble in water under neutral or alkaline conditions than under acidic conditions at 25°C.

Preferably, the barrier layer is in contact with the wound facing hydrogel layer, and it may be bonded thereto chemically or physically. Preferably, the hydrogel layer comprises an acidic buffer, such as a mixture of a weak water-soluble acid and its conjugate base.

In use, the hydrogel layer absorbs and buffers wound exudate to provide a moist and preferably slightly acidified wound environment suitable for healing. As the hydrogel layer becomes saturated with wound exudate, which is neutral or slightly alkaline, its pH rises until it reaches a range at which the pH-sensitive material in the barrier layer starts to dissolve. This breakdown of the pH-sensitive material increases the liquid permeability of the barrier layer and thereby allows the excess exudate to escape through the barrier layer, preferably into an absorbent layer. Thus, the layered material is suitable for the treatment of wounds having a range of different exudation rates, and for extended periods.

Preferably, the layered material according to the invention further comprises an absorbent layer separated from the wound facing hydrogel layer by the barrier layer. The area of the optional absorbent layer is typically in the range of from 1cm^2 to 200cm^2, more preferably from 4cm^2 to 100cm^2.

The optional absorbent layer may be any of the layers conventionally used for absorbing wound fluids, serum or blood in the wound healing art, including gauzes, nonwoven fabrics, superabsorbents, hydrogels and mixtures thereof. Preferably, the absorbent layer comprises a layer of absorbent foam, such as an open celled hydrophilic polyurethane foam prepared in accordance with EP-A-0541391, the entire content of which is expressly incorporated herein by reference. In other embodiments, the absorbent layer may be a nonwoven fibrous web, for example a carded web of viscose staple fibers. The basis weight of the absorbent layer may be in the range of 50-500g/m^2, such as 100-400g/m^2. The uncompressed thickness of the absorbent layer may be in the range of from 0.5mm to 10mm, such as 1mm to 4mm. The free (uncompressed) liquid absorbency measured for physiological saline may be in the range of 5 to 30 g/g at 25°C.

Preferably the layered wound dressing material according to the invention further comprises a reservoir of antimicrobial material over the barrier layer opposite the hydrogel layer. The reservoir is preferably a layer of antimicrobial-containing material. For example, the antimicrobial layer may be coated over the barrier

layer, or it may be dispersed in the absorbent layer. The antimicrobial is only released into the wound after the barrier layer is dissolved by the action of wound exudate. This enables selective release of the antimicrobial only into exuding wounds, such as infected wounds. Suitable antimicrobials include antibiotics, silver salts and chlorhexidine. Preferred amounts of the antimicrobials are from 0.01 to 100 mg/cm^2 of the barrier layer, more preferably from 0.1 to 10 mg/cm^2.

Preferably the layered wound dressing material according to the invention further comprises a liquid-impermeable backing layer over the barrier layer and the absorbent layer and antimicrobial reservoir (where present) opposite the hydrogel layer. The backing layer supports the barrier layer and the intermediate absorbent layer and antimicrobial reservoir (where present) and preferably provides a barrier to passage of microorganisms through the dressing. The backing layer may extend beyond at least one edge of the absorbent layer to provide an adhesive-coated margin adjacent to the said edge for adhering the dressing to a surface, such as to the skin of a patient adjacent to the wound being treated. An adhesive-coated margin may extend around all sides of the absorbent layer, so that the dressing is a so-called island dressing. However, it is not necessary for there to be any adhesive-coated margin.

Preferably, the backing layer is substantially liquid-impermeable. The backing layer is preferably semipermeable. That is to say, the backing layer is preferably permeable to water vapour, but not permeable to liquid water or wound exudate. Preferably, the backing layer is also microorganism-impermeable. Suitable continuous conformable backing layers will preferably have a moisture vapor transmission rate (MVTR) of the backing layer alone of 300 to 5000 g/m^2/24hrs, preferably 500 to 2000 g/m^2/24hrs at 37.5 °C at 100% to 10% relative humidity difference. The backing layer thickness is preferably in the range of 10 to 1000 micrometers, more preferably 100 to 500 micrometers.

The MVTR of the dressing according to the present invention as a whole is lower than that of the backing layer alone, because the barrier layer partially obstructs moisture transfer through the dressing. Preferably, the MVTR of the dressing

(measured across the island portion of the dressing) is from 20% to 80% of the MVTR of the backing layer alone, more preferably from 20% to 60% thereof, and most preferably about 40% thereof. It has been found that such moisture vapor transmission rates allow the wound under the dressing to heal under moist conditions without causing the skin surrounding the wound to macerate.

Suitable polymers for forming the backing layer include polyurethanes and poly alkoxyalkyl acrylates and methacrylates such as those disclosed in GB-A-1280631. Preferably, the backing layer comprises a continuous layer of a high density blocked polyurethane foam that is predominantly closed-cell. A suitable backing layer material is the polyurethane film available under the Registered Trade Mark ESTANE 5714F.

The adhesive layer (where present) should be moisture vapor transmitting and/or patterned to allow passage of water vapor therethrough. The adhesive layer is preferably a continuous moisture vapor transmitting, pressure-sensitive adhesive layer of the type conventionally used for island-type wound dressings, for example, a pressure sensitive adhesive based on acrylate ester copolymers, polyvinyl ethyl ether and polyurethane as described for example in GB-A-1280631. The basis weight of the adhesive layer is preferably 20 to 250 g/m^2, and more preferably 50 to 150 g/m^2. Polyurethane-based pressure sensitive adhesives are preferred.

Preferably, the hydrogel layer has a dry basis weight of from 10 to 200g/m^2, more preferably from 10 to 100g/m^2, and most preferably from 10 to 50g/m^2.

The term "hydrogel layer" refers generally to layers that interact with the wound surface under physiological conditions to maintain an elevated moisture level at the wound surface. Preferably, the hydrogel layer forms a gel with water under physiological conditions. Such hydrogel layers can be formed by the inclusion of medically acceptable macromolecular materials that preferably have the ability to swell and absorb fluid while maintaining a strong integral structure. Preferably, the hydrogel composition forms a gel or emulsion that is substantially insoluble in water under physiological conditions, whereby the hydrogel is not washed away by

the wound fluid. The hydrogel may be a biopolymer, and/or it may be bioabsorbable. That is to say, it may undergo gradual resorption *in vivo*.

Exemplary insoluble gels include certain cross-linked polyacrylate gels, calcium alginate gels, cross-linked hyaluronate gels, wherein the hydrogel layer comprises a hydrogel material selected from gels formed from vinyl alcohols, vinyl esters, vinyl ethers and carboxy vinyl monomers, meth(acrylic) acid, acrylamide, N-vinyl pyrrolidone, acylamidopropane sulphonic acid, PLURONIC (Registered Trade Mark) (block polyethylene glycol, block polypropylene glycol) polystyrene-, maleic acid, NN-dimethylacrylamide diacetone acrylamide, acryloyl morpholine, and mixtures thereof. Preferably, the gel adheres strongly to the surface of the barrier layer material to resist washing off by wound fluid. In certain embodiments the gel may be chemically bonded to the surface of the barrier layer.

Preferably, the hydrogel layer comprises a hydrogel material selected from polyurethane gels, biopolymer gels, carboxymethyl cellulose gels, hydroxyethyl cellulose gels, hydroxy propyl methyl cellulose, modified acrylamide and mixtures thereof. Suitable biopolymer gels include alginates, pectins, galactomannans, chitosan, gelatin, hyaluronates and mixtures thereof. Some of these biopolymer materials also promote wound healing.

Preferably, the gels are cross-linked, and the cross-linking may be either covalent or ionic. It will be appreciated that the degree of cross linking will influence the physical properties and rate of resorption of the hydrogel layer *in vivo*.

Preferably, the hydrogel material further comprises from 5 to 50% by weight on a dry weight basis of one or more humectants such as glycerol

Preferably, the hydrogel layer comprises a hydrogel material of the kind described in WO00/07638, the entire content of which is incorporated herein by reference.

Alternatively or additionally to the gel-forming macromolecules, the hydrogel layer may comprise one or more emollients. Emollients are used to smooth the surface

of skin and to increase the degree of hydration. They act either by occluding water loss from the outer layer of the skin, or by improving water binding to the skin. Emollients are particularly useful in the treatment of atopic eczemas and ichthyoses. Preferred emollients include White Soft Paraffin, Yellow Soft Paraffin, Liquid paraffin, Urea Creams, Lanolin, Sodium Pyrrolidone Carboxylate (PCA Na), Evening primrose extract (gamma linolenic acid), Soya Oil, Tea Tree Oil, Coconut Oil, Almond Oil, Camomile Extract, Cod Liver Oil, Peanut Oil, Emu Oil, Aloe Vera, Sunflower oil, Avocado Oil, Jojoba Oil, Cocoamide, and mixtures thereof.

The hydrogel layer may additionally comprise one or more active therapeutic or antimicrobial agents. Suitable therapeutic agents include growth factors, analgesics, local anaesthetics and steroids. Suitable antimicrobial agents include antiseptics such as silver compounds and chlorhexidine, and antibiotics. The therapeutic or antimicrobial agents are usually added in an amount of from 0.01% to 5% by weight, based on the dry weight of the hydrogel layer.

The hydrogel layer may be continuous or discontinuous. The hydrogel layer may be applied by spraying or by a printing or transfer process.

The hydrogel material may be inherently acidic, for example it may comprise a polymeric gel-forming acid such as hyaluronic acid, alginic acid, pectic acid, or a polymer or copolymer of an acrylic acid. Alternatively or additionally, the layered wound dressing material according to the present invention preferably comprises a weak, water-soluble acid buffer system dissolved or dispersed in the hydrogel.

Preferably, the acid buffer system is present in an amount of at least 0.1 mmol/g, preferably at least 0.2 mmol/g, more preferably at least 0.3 mmol/g. The upper limit of the amount of acid buffer system is preferably about 5.0 mmol/g, more preferably about 2.0 mmol/g. The amount of acid buffer system is calculated as the total weight of water-soluble weak acid plus the total weight of water-soluble conjugate base. The amount is based on the dry weight of the hydrogel material.

The acid buffer system is a combination of one or more physiologically acceptable weak water-soluble acids with one or more physiologically acceptable water-soluble conjugate bases of weak acids. Preferably, the conjugate base is a conjugate base of the weak acid present in the system. Preferably, the acid components of the water-soluble acid buffer system have a pK_a in the range of from 3.5 to 6.5.

The presence of a buffer system comprising both a weak acid and a conjugate base enables the materials according to the present invention to maintain a stable pH in a wound environment over an extended period of time during which gradual neutralisation of the acid is taking place, in accordance with well known physicochemical principles. For good buffering performance, the molar ratio of acid to base in the buffer system should be in the range of from 1:10 to 10:1, preferably from 1:5 to 5:1, and more preferably from 2:5 to 5:2.

Preferably, the water-soluble acid has a low vapour pressure, and more preferably it is solid when anhydrous at room temperature. Preferably, the water-soluble acid has a solubility of at least 10 mg/ml at 25°C in water, more preferably at least 20 mg/ml, and still more preferably at least 50 mg/ml.

Wound dressings based on macromolecular acids such as alginic acid, certain viscose fibres, or oxidized regenerated cellulose are known. However, these macromolecular acids have limited solubility, limited buffering capacity and provide little ability to control the pH at a wound surface. The water-soluble acid according to the present invention is preferably not a macromolecular substance.

The weak, water-soluble acid buffer system provides a mildly acidic (preferably pH 3.5 to 5.5) environment at the wound surface. Accordingly, the water-soluble acid component of the buffer system preferably has a pK_a in the range of from 3 to 8, more preferably from 3.5 to 6.5. Preferably, the conjugate base is the conjugate base of the water-soluble acid present in the material, for example a salt of the weak water-soluble acid, more preferably a sodium salt thereof.

Preferably, the weak water-soluble acid and conjugate base are selected from the group consisting of water-soluble organic carboxylic acids and dihydrogen phosphate salts, and mixtures and conjugate bases thereof. The preferred organic carboxylic acids include C_2-C_6 alkanoic acids, benzoic acid, substituted benzoic acids, citric acid, tartaric acid, malic acid, lactic acid, succinic acid, and ascorbic acid. It goes without saying that the water-soluble acid and conjugate base used in the materials according to the present invention should be fully biologically and pharmaceutically acceptable for topical application to a wound.

Preferably, the water-soluble acid and the conjugate base are both non-volatile. More preferably, both materials are solids when pure and anhydrous at 25°C. The most preferred buffer system is hydrogen phosphate/dihydrogen phosphate. Other highly preferred systems are citric acid/citrate and lactic acid/lactate. Sodium salts or sodium/potassium mixed salts of the conjugate bases are preferred.

The concentration of the weak, water-soluble acid in the hydrogel layer of the material according to the present invention will depend on the particular application, the nature of the wound to which the material is to be applied, and the desired rate of breakdown of the hydrogel and barrier layers in use.

The acid buffering capacity of the hydrogel layer according to the present invention can be determined, for example, by slurrying 1 g of the hydrogel layer in 10 mls of deionised water and measuring the amount of alkali (sodium hydroxide) needed to raise the pH of the slurry to 10. The acid buffering capacity of the material is preferably at least 0.05 mmol/g, more preferably at least 0.1 mmol/g, and most preferably at least 0.2 mmol/g, based on the dry weight of the hydrogel layer

The layered material according to the present invention preferably provides a pH at the wound site in use in the range of from 3.5 to 6.5, more preferably from

4.5 to 6.5. As more exudate is produced, it neutralises the acid present in the hydrogel and increases the pH of the hydrogel layer until it reaches a range at which dissolution of the pH sensitive material takes place.

Preferably, the pH-sensitive material is substantially insoluble in water at 25°C and pH 4 and substantially soluble in water at 25°C and pH 8. Preferably, the polymer becomes soluble with increasing pH at a pH in the range of 5 to 7, more preferably 5.5 to 6.5. In this context the term "soluble" preferably denotes an equilibrium solubility of the material greater than 1%w/w in water at 25°C. Particularly suitable are film-forming polymers and mixtures, such as those used to provide enteric coatings on orally administered medicaments.

Preferably, the pH-sensitive material comprises a polymer selected from the group consisting of cellulose derivatives, starch derivatives, pectins, polyacrylates, polyvinyl acetate phthalate, and mixtures thereof.

Preferred cellulose derivatives are selected from cellulose acetate phthalate, cellulose acetate trimellitate, hydroxypropyl methyl cellulose, hydroxypropyl methyl cellulose acetate succinate, carboxymethyl ethyl cellulose, oxidised regenerated cellulose, and mixtures thereof.

Preferred polyacrylates are selected from the copolymers of methacrylic acid with methyl methacrylate. Particularly preferred are various copolymers of this type sold under the Registered Trade Mark EUDRAGIT. By varying the ratio of methacrylic acid to methyl methacrylate it is possible to control the pH at which these copolymers dissolve in order to optimise the properties of the material.

The barrier layer is preferably substantially liquid-impermeable before dissolution of the pH-sensitive material. In certain embodiments the barrier layer comprises a substantially continuous film comprising the pH-sensitive material, and preferably consisting essentially of the pH-sensitive material, optionally mixed with plasticisers, fillers, indicator substances, or medicating agents.

In other preferred embodiments, the barrier layer comprises a liquid-permeable support layer having the pH-sensitive material applied thereto, preferably in occlusive fashion to reduce the liquid permeability of the layer until the pH-sensitive material is dissolved. For example, the support layer may comprise a water-insoluble perforated film or nonwoven or woven fabric having the pH-sensitive material coated thereon in partially or completely occlusive fashion.

The present invention further provides a wound dressing comprising a barrier layer, wherein the barrier layer comprises a pH-sensitive material that is substantially insoluble in water at 25°C under acidic conditions, but substantially soluble in water at 25°C under neutral or alkaline conditions. Preferably, the composition of the barrier layer is as described above in connection with the layered structures according to the present invention. Preferably, the wound dressing further comprises an absorbent layer and/or a reservoir of antimicrobial and/or a backing layer and/or any other preferred features as described above in connection with preferred embodiments of the layered structures according to the invention.

Preferably, a liquid-absorbent layer is provided on the wound contacting side of the wound dressing over the barrier layer. A further liquid-permeable wound contacting top sheet may also be provided. Preferably, the barrier layer in the wound dressing according to the present invention forms part of a layered wound dressing material according to the present invention as described above.

Preferably, the wound dressing according to the invention further comprises one or more protective cover sheets over the hydrogel layer and any exposed adhesive. For example, the cover sheets may comprise one or more release-coated paper cover sheets. Preferably, the dressing is sterile and packaged in a microorganism-impermeable container.

The present invention further provides a method of controlling the absorption of wound exudate from a wound site by contacting a pH-sensitive barrier layer with the wound exudate, wherein the wound exudate dissolves the barrier layer thereby

allowing increased passage of exudate from the wound site. Preferably, the composition of the barrier layer is as described above in connection with the layered structures according to the present invention. Preferably, the method further comprises applying the barrier layer in a wound dressing further comprising an absorbent layer and/or a reservoir of antimicrobial and/or a backing layer and/or any other preferred features as described above in connection with preferred embodiments of the wound dressings according to the invention.

Preferably, the pH-sensitive barrier layer is the barrier layer of a layered structure according to the present invention.

An embodiment of the present invention will now be described further, by way of example, with reference to the accompanying drawings, in which:

Figure 1 shows a perspective view of the lower (wound contacting) surface of a wound dressing according to the invention with the barrier layer and the hydrogel layer partially cut away; and

Figure 2 shows a partial transverse cross section (not to scale) through the island region of the dressing of Figure 1.

Referring to Figure 1, the wound dressing 1 is an island-type self-adhesive wound dressing comprising a backing layer 2 of microporous liquid-impermeable polyurethane foam, such as ESTANE 5714F (Registered Trade Mark). The backing layer is permeable to water vapor, but impermeable to wound exudate and microorganisms.

The backing layer 2 is coated with a substantially continuous layer 3 of pressure-sensitive polyurethane adhesive. An absorbent island 4 is adhered to a central region of the adhesive-coated backing sheet 2.

The absorbent island 4 comprises an absorbent layer 5 of hydrophilic polyurethane foam prepared as described in EP-A-0541391 and having a basis weight of about 350g/m^2 and a thickness of about 1.5 mm.

A barrier layer extends over the absorbent layer 5 and is wrapped partially around the absorbent layer 5, and the edges 7 of the barrier layer are adhered to the backing layer 2 behind the absorbent layer 5 by the adhesive 3. This can be seen more clearly in Figure 2. The barrier layer consists of a support layer 6 of vacuum mesh-perforated ethylene methyl acrylate (EMA) film coated with an occlusive layer 8 of poly(methyl methacrylate/methyl acrylate) pH-sensitive polymer.

Referring to Figure 2, the barrier layer presents a continuous top surface to the wound This surface is coated with a layer of hydrogel 9 applied by spraying. The hydrogel 9 has a dry basis weight of 30g/m^2 and consists of bovine gelatin cross-linked with glutaraldehyde or formaldehyde. The hydrogel layer 9 contains about 10% by weight on a dry weight basis of a sodium hydrogen phosphate/sodium dihydrogen phosphate buffer.

The wound facing surface of the dressing shown in Figure 1 is protected by two silicone-coated release papers 10,11. The dressing is packaged in a microorganism-impermeable pouch (not shown), and sterilised using gamma radiation.

In use, the dressing 1 is removed from the package, the release papers 10,11 are removed, and the dressing is adhered to the skin around the wound by the adhesive layer 3, with the barrier layer and hydrogel 9 in contact with the wound to provide a sterile and absorbent dressing. The hydrogel 9 absorbs wound exudate and maintains a moist and slightly acid-buffered environment at the wound surface. As more exudate is produced, it neutralises the hydrogel layer and the pH-sensitive polymer 8 on the barrier layer dissolves, allowing the excess exudate to escape through the support layer 6 into the absorbent layer 5. In this way, the dressing can provide an improved wound healing environment for an extended time on both high- and low- exuding wounds. Furthermore, the dissolution of the barrier layer can trigger the release of antimicrobial active agents from the absorbent layer into the wound in response to increased exudate production by infected wounds.

The above embodiment has been described by way of example only. Many other embodiments falling within the scope of the accompanying claims will be apparent to the skilled reader.

CLAIMS

1. A layered wound dressing material comprising:

a wound facing hydrogel layer; and

a barrier layer, wherein the barrier layer comprises a pH-sensitive material that is substantially insoluble in water at 25°C under acidic conditions, but substantially soluble in water at 25°C under neutral or alkaline conditions.

2. A layered wound dressing material according to claim 1, wherein the barrier layer is in contact with the wound facing hydrogel layer.

3. A layered wound dressing material according to claim 1 or 2, further comprising an absorbent layer separated from the wound facing hydrogel layer by the barrier layer.

4. A layered wound dressing material according to claim 3, further comprising a liquid-impermeable backing layer over the absorbent layer opposite the barrier layer.

5. A layered wound dressing material according to claim 4, wherein the backing layer is adhesive-coated and extends beyond at least one edge of the wound facing hydrogel layer and the barrier layer.

6. A layered wound dressing material according to any preceding claim, wherein the hydrogel layer has a dry basis weight of from 10 to 200g/m^2.

7. A layered wound dressing material according to any preceding claim, wherein the hydrogel layer comprises a hydrogel material selected from polyurethanes, biopolymers, carboxymethyl cellulose, hydroxyethyl cellulose, hydroxypropyl methyl cellulose, modified acrylamides and mixtures thereof.

8. A layered wound dressing material according to any preceding claim, wherein the hydrogel layer comprises a hydrogel material selected from vinyl

alcohols, vinyl esters, vinyl ethers and carboxy vinyl monomers, meth(acrylic) acid, acrylamide, N-vinyl pyrrolidone, acylamidopropane sulphonic acid, pluronic (block polyethylene glycol, block polypropylene glycol)polystyrene maleic acid, NN-dimethylacrylamide, diacetone acrylamide or acryloyl morpholine.

9. A layered wound dressing material according to any preceding claim, wherein the hydrogel layer comprises an emollient.

10. A layered wound dressing material according to claim 9, wherein the emollient is selected from the group consisting of white soft paraffin, yellow soft paraffin, liquid paraffin, urea creams, lanolin, sodium pyrrolidone carboxylate, evening primrose extract (gamma linolenic acid), soya oil, tea tree oil, coconut oil, almond oil, camomile extract, cod liver oil, peanut oil, emu oil, aloe vera, sunflower oil, avocado oil, jojoba oil, cocoamide, and mixtures thereof.

11. A layered wound dressing material according to any preceding claim, wherein the hydrogel layer comprises an active therapeutic agent or an antimicrobial agent.

12. A layered wound dressing material according to claim 11, wherein the hydrogel layer comprises a silver compound.

13. A layered wound dressing material according to any preceding claim, wherein the hydrogel layer comprises a weak water-soluble acid buffer system.

14. A layered wound dressing material according to claim 13, wherein the weak water-soluble acid buffer system is present in an amount of at least 0.2 mmol/g.

15. A layered wound dressing material according to claim 13 or 14, wherein the weak water-soluble acid buffer system is present in an amount of from 0.3 to 2.0 mmol/g.

16. A layered wound dressing material according to any one of claims 13 to 15, wherein the acid component(s) of the water-soluble acid buffer has/have a pK_a in the range of from 3.5 to 6.5.

17. A layered wound dressing material according to any preceding claim, wherein the hydrogel layer has an acid buffering capacity of at least 0.05 mmol/gram dry weight of the hydrogel layer.

18. A layered wound dressing material according to claim 17, wherein the hydrogel layer has an acid buffering capacity of at least 0.1 mmol/g.

19. A layered wound dressing material according to any one of claims 13 to 18, wherein the weak water-soluble system is selected from the group consisting of water-soluble organic carboxylic acids and dihydrogen phosphate salts, and mixtures thereof in combination with one or more conjugate bases thereof.

20. A layered wound dressing material according to claim 19, wherein said organic carboxylic acids are selected from the group consisting of C_2-C_6 alkanoic acids, benzoic acid, substituted benzoic acids, citric acid, tartaric acid, malic acid, lactic acid, succinic acid and ascorbic acid.

21. A layered wound dressing material according to any one of claims 13 to 20, wherein said weak water-soluble buffer system comprises sodium hydrogen phosphate/sodium dihydrogen phosphate.

22. A layered wound dressing material according to any preceding claim, wherein a 10%w/v dispersion (dry weight basis) of said hydrogel material in water provides an equilibrium pH at 25°C of from 4.5 to 6.5.

23. A layered wound dressing material according to any preceding claim, wherein the water-soluble acid and the conjugate base of said buffer system are both solids when anhydrous at 25°C.

24. A layered wound dressing material according to any preceding claim, wherein the pH-sensitive material comprises a polymer that is substantially insoluble in water at 25°C and pH4 and soluble in water at 25°C and pH8.

25. A layered wound dressing material according to any preceding claim, wherein the pH-sensitive material comprises a polymer selected from the group consisting of cellulose derivatives, starch derivatives, pectins, polyacrylates, polyvinyl acetate phthalate, and mixtures thereof.

26. A layered wound dressing material according to any preceding claim, wherein the pH-sensitive material comprises a cellulose derivative selected from cellulose acetate phthalate, cellulose acetate trimellitate, hydroxypropyl methyl cellulose, hydroxypropyl methyl cellulose acetate succinate, carboxymethyl ethyl cellulose, oxidised regenerated cellulose, and mixtures thereof.

27. A layered wound dressing material according to any preceding claim, wherein the pH-sensitive material comprises a polyacrylate selected from the copolymers of methacrylic acid with methyl methacrylate.

28. A layered wound dressing material according to any preceding claim, wherein the barrier layer comprises a substantially continuous film of the pH-sensitive material.

29. A layered wound dressing material according to any preceding claim, wherein the barrier layer comprises a liquid-permeable support layer having the pH-sensitive material applied thereto.

30. A layered wound dressing material according to any preceding claim, further comprising a reservoir of a medicament for the treatment of wound infection on the side of the barrier layer opposite to the hydrogel layer.

31. A layered wound dressing material according to claim 30, wherein the medicament is dispersed in an absorbent layer.

32. A wound dressing comprising a barrier layer, wherein the barrier layer comprises a pH-sensitive material that is substantially insoluble in water at 25°C under acidic conditions, but substantially soluble in water at 25°C under neutral or alkaline conditions.

33. A wound dressing according to claim 32, further comprising a liquid-absorbent layer on the wound facing side of the barrier layer.

34. A wound dressing according to claim 32, wherein the barrier layer forms part of a layered wound dressing material according to any one of claims 1 to 31.

35. A method of controlling the absorption of wound exudate from a wound site by contacting a pH-sensitive barrier layer with the wound exudate, wherein the wound exudate dissolves the barrier layer thereby allowing increased passage of exudate from the wound site.

36. A wound dressing according to claim 35, wherein a liquid-absorbent layer is provided on the wound facing side of the barrier layer.

37. A method according to claim 36, wherein the pH-sensitive barrier layer is the barrier layer of a layered structure according to any one of claims 1 to 29.

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Claims searched:	1-34 & 36	**Date of search:**	2 May 2001

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Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

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Other: Online: EPODOC, WPI, PAJ

Documents considered to be relevant:

Category	Identity of document and relevant passage		Relevant to claims
A	GB 2175211 A	(PROCTER & GAMBLE) p.1, l.59 - p.2, l.2; claim 1.	1
A	WO 99/45976 A1	(PROCTER & GAMBLE) p.4, ll.6-14; p.14, ll.17-22; claim 1.	1
A	WO 98/57677 A1	(SCA MÖLNLYCKE) p.3, ll.10-21; p.5, ll.3-30.	1

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
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